

148. (New Claim) A method for identifying a compound that decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

- (a) contacting efp with a compound; and
- (b) determining whether said compound decreases activity of efp, wherein efp is isolated from a prokaryotic organism.

149. (New Claim) A method for identifying a compound that decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

- (a) contacting efp with a compound; and
- (b) determining whether said compound decreases activity of efp, wherein efp is isolated from a bacteria.

150. (New Claim) A method for identifying a compound that decreases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

- (a) contacting efp with a compound; and
- (b) determining whether said compound decreases activity of efp, wherein efp is isolated from a bacteria selected from the group consisting of *E. coli*, *S. aureus*, *S. pneumoniae*, *H. influenzae*, and an *Enterococcus* species.

REMARKS

Claims 1-8, 15-18, 140 and 141 are pending in the present application. Claims 1-3 have been cancelled herein. Claims 4-8, 15-18, and 141 have been amended herein. New claims 142-150 have also been added herein. No new matter has been added. Upon entry of the present amendment, claims 4-8, 15-18, 140-150 will be pending. Applicants have amended all claims to be independent.

I. The Claims Are Clear And Definite

Claims 1-8 and 15-18 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicants regard as their invention. The Advisory Action asserts that the phrase “increases or decreases” is indefinite. Although Applicants disagree, solely to advance prosecution of the present application, the claims have been amended according to the Examiner’s recommendation. Claims 4-8 and 15-18 have been amended to recite “increases” and new claims 142-150, which recite “decreases,” have been added. No new matter has been added. Thus, the claims are definite within the meaning of § 112. *In re Mercier*, 185 U.S.P.Q. 774 (C.C.P.A. 1975) (claims sufficiently define an invention so long as one skilled in the art can determine what subject matter is or is not within the scope of the claims).

The Advisory Action mailed March 12, 2002 asserts that amended claim 141 now recites “modulating” which was previously deleted from the claims based on a rejection made in Paper No. 14 under 35 U.S.C. § 112, second paragraph. Claim 141, prior to its amendment to be an independent claim, was dependent upon claim 140. Claim 140 recites “modulating.” Significantly, claim 140 was never rejected under 35 U.S.C. § 112, second paragraph, for reciting “modulating.” Thus, when Applicants amended claim 141 to be an independent claim, they simply incorporated the language of the base claim, which was not rejected. Applicants teach, for example, at page 10, lines 12-13 of the specification that modulates means “an increase or decrease.” The Examiner has utterly failed to provide any evidence or reasoning why one skilled in the art would not be able to determine the metes and bounds of “an increase or decrease.”

The Advisory Action mailed March 12, 2002 also asserts that the phrase “in association” in claim 141 is unclear. Claim 141 recites, in part, “said L16 protein in association with efp.” One skilled in the art having examined Applicants’ specification in proper context would readily understand that the L16 protein would be bound to or form a complex with efp and, thus, would be “in association” with efp. In such a complex with efp, the L16 protein could interact directly with efp or could interact indirectly with efp via other components of the complex.

In view of the foregoing, Applicants request that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

II. The Claimed Invention Is Enabled

Claims 1-8, 15-18, 140 and 141 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to provide a disclosure that is enabling for the full scope of the claims. Although Applicants maintain that one skilled in the art would be able to practice the claimed invention without being required to perform undue experimentation, solely to advance prosecution of the present application, Applicants have amended the claims in a manner recommended by the Examiner. In particular, claims 1-3 have been cancelled without prejudice to their presentation in another application. In addition, claims 4-8 and 15-18 have been amended to recite “increases.” Further, new claims 142-150 have been added and which recite “decreasing.”

The Advisory Action mailed March 12, 2002 notes that claim 4, for example, recites “increased or decreased” in regard to the intrinsic fluorescence as asserts that one skilled in the art would be required to perform undue experimentation to determine if “an increase or decrease is produced and what activity of the prokaryotic elongation factor p is affected by the identified compound.” No amount of undue experimentation is required to determine whether the intrinsic fluorescence of efp is increased or decreased. Applicants teach, for example, at page 15, lines 13 to 23 of the specification, preferred methodology for measuring intrinsic fluorescence. Of course, other methodology known to the skilled artisan can also be applied. Further, Applicants provide a working example of measuring intrinsic fluorescence of efp (see, Example 2). Thus, there is no doubt that one skilled in the art would **not** be required to perform any amount of undue experimentation to determine if “an increase or decrease” in the intrinsic fluorescence of efp is produced.

In regard to determining “what activity of the prokaryotic elongation factor p is affected by the identified compound,” the Examiner is reminded that “activity” has been defined by Applicants to mean a variety of measurable indicia suggesting or revealing binding, either direct or indirect, including, for example, the affinity of a compound for directly binding efp or a ribosome, or, for example, measurement of amounts of upstream or downstream proteins or other similar functions after some stimulus or event. Thus, referring to claim 4 for example, by determining whether a compound binds to efp by measuring the intrinsic fluorescence of efp, the “activity” of efp is, in fact, determined as well. Thus, if a particular compound decreases the fluorescence intensity of efp, the

compound binds to efp. Applicants teach, for example, at page 15, lines 4 to 6 of the specification that whether a compound modifies the activity of the efp (*i.e.*, increases or decreases the activity) is determined by, for example, determining whether the compound binds to efp. Thus, no amount of undue experimentation is required to carry out the claimed inventions.

The Advisory Action mailed March 12, 2002 also asserts that the specification lacks exemplification of a specific assay to assay a specific compound. Applicants' specification, however, provides at least six examples (see, Examples 1-6) which provide detailed methodology for assaying compounds. Each of the assays set forth in Examples 1-6 can be carried out using any test compound. There is no requirement for Applicants to identify any "specific assay" to identify a "specific compound." The Office Action fails to provide any reasoning or evidence indicating that the assays disclosed in the specification could not be carried out with any compound.

In view of the foregoing, Applicants request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

III. Conclusion

The present claims are in condition for allowance and an early notice of the same is earnestly solicited. If, for any reason, the present application fails to proceed to allowance, the Examiner is encouraged to contact Applicants' undersigned representative at (215) 564-8906. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1-3 have been cancelled.

New claims 142-150 have been added.

Claims 4-8, 15-18 and 141 have been amended as follows:

4. (Amended) [The method of claim 3] A method for identifying a compound that increases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

- (a) contacting efp with a compound; and
- (b) determining whether said compound binds to efp by measuring the intrinsic fluorescence of efp and determining whether said intrinsic fluorescence is increased or decreased by said binding, wherein said intrinsic fluorescence of efp is measured as a function of the tryptophan residue(s) of efp.

5. (Amended) [The method of claim 4] A method for identifying a compound that increases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

- (a) contacting efp with a compound; and
- (b) determining whether said compound binds to efp by measuring the intrinsic fluorescence of efp and determining whether said intrinsic fluorescence is decreased by said binding, wherein said intrinsic fluorescence of efp is measured as a function of the tryptophan residue(s) of efp, wherein said fluorescence of efp is measured and compared to the fluorescence intensity of efp in the presence of the compound, wherein a decrease in fluorescence intensity indicates binding of efp.

6. (Amended twice) [The method of claim 1 further comprising step:] A method for identifying a compound that increases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

- (a) contacting efp with a compound;

- (b) determining whether said compound increases activity of efp; and
- (c) determining whether said compound which [modulates] increases the activity of efp [modifies] increases the activity of other protein(s) essential for the functioning of efp.

7. (Amended) [The method of claim 6] A method for identifying a compound that increases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

- (a) contacting efp with a compound;
- (b) determining whether said compound increases activity of efp; and
- (c) determining whether said compound that increases the activity of efp increases the activity of [wherein said other protein essential for the functioning of efp is] L16 protein.

8. (Amended) [The method of claim 2 wherein step (b) comprises] A method for identifying a compound that increases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

- (a) contacting efp with a compound; and
- (b) determining whether said compound binds to efp by a binding assay selected from the group consisting of gel electrophoresis, Western blot, filter binding, and scintillation proximity assay.

15. (Amended twice) [The method of claim 1] A method for identifying a compound that increases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

- (a) contacting efp with a compound; and
- (b) determining whether said compound increases activity of efp, wherein efp is isolated from a natural source.

16. (Amended) [The method of claim 15 wherein said natural source is] A method for identifying a compound that increases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

- (a) contacting efp with a compound; and

(b) determining whether said compound increases activity of efp, wherein efp is isolated from a prokaryotic organism.

17. (Amended) [The method of claim 16 wherein said prokaryotic organism is] A method for identifying a compound that increases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound; and

(b) determining whether said compound increases activity of efp, wherein efp is isolated from a bacteria.

18. (Amended) [The method of claim 17 wherein said bacteria is] A method for identifying a compound that increases the activity of prokaryotic elongation factor p (efp) comprising the steps of:

(a) contacting efp with a compound; and

(b) determining whether said compound increases activity of efp, wherein efp is isolated from a bacteria selected from the group consisting of *E. coli*, *S. aureus*, *S. pneumoniae*, *H. influenzae*, and an *Enterococcus* species.

141. (Amended) [A method of claim 140] A method of modulating the activity of L16 protein comprising contacting said L16 protein in association with efp with an oxazolidinone compound, wherein said L16 protein in association with efp is in a cell or cell preparation.